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Organon Reports Results for the Second Quarter Ended June 30, 2023

- Second quarter 2023 revenue of \$1,608 million
- Second quarter 2023 diluted earnings per share of \$0.95 and non-GAAP Adjusted diluted earnings per share of \$1.31
- Adjusted EBITDA of \$530 million
- Board of Directors declares quarterly dividend of \$0.28 per share
- Full year 2023 financial guidance ranges updated:
 - Revenue range narrowed to \$6.25 billion to \$6.45 billion, primarily reflecting current foreign currency exchange rates
 - Adjusted EBITDA margin range now 31.5%-33.0% to incorporate current visibility on IPR&D (in-process research and development) and milestones

Jersey City, N.J., August 8, 2023 – Organon (NYSE: OGN) today announced its results for the second quarter ended June 30, 2023.

"During the second quarter of 2023, Organon continued to build on its track record, delivering solid volume growth across all regions and franchises. The Women's Health and Biosimilars franchise revenue grew 10% and 15% excluding the impact of foreign currency ("ex-FX"), respectively, and Established Brands continued to demonstrate stability," said Kevin Ali, Organon's CEO. "Further, on July 1st we launched *Hadlima*[™] (adalimumab-bwwd) in the United States - so far our biggest commercial launch in the U.S. as a standalone company. *Hadlima* is emerging as one of a few biosimilars offerings earning commercial success so far. We are encouraged by our early traction and remain confident in our strategy, the attributes of our product and our collaborator's capabilities to deliver reliable supply."

Second Quarter 2023 Revenue

in \$ millions	Q2 2023	Q2 2022	VPY	VPY ex-FX
Women's Health	\$ 438	\$ 408	8%	10%
Biosimilars	135	119	14%	15%
Established Brands	995	1,018	(2)%	—%
Other ⁽¹⁾	40	40	(2)%	(1)%
Revenues	\$ 1,608	\$ 1,585	1%	4%

(1) Other includes manufacturing sales to Merck & Co., Inc., Rahway, NJ, USA and other third parties.

For the second quarter of 2023, total revenue was \$1,608 million, an increase of 1% as-reported and an increase of 4% excluding the impact of foreign currency (ex-FX), compared with the second quarter of 2022.

Women's Health revenue increased 8% on an as-reported basis, and increased 10% ex-FX in the second quarter of 2023 compared with the second quarter of 2022 driven primarily by a 12% ex-FX increase in *Nexplanon*® (etonogestrel implant), a long-acting reversible contraceptive. The Women's Health franchise also benefited from 17% ex-FX growth in the fertility portfolio during the quarter due to COVID-19 recovery in China as well as strong demand in the LAMERA region and in the U.S. Growth in the Women's Health franchise was partially offset by a 3% ex-FX decrease of *NuvaRing*® (etonogestrel/ethinyl estradiol vaginal ring) which continues to be impacted by generic competition.

Biosimilars revenue increased 14% as-reported and 15% ex-FX in the second quarter of 2023, compared with the second quarter of 2022 primarily driven by *Renflexis*® (infliximab-abda) which grew 20% ex-FX due to continued demand and strong volume growth in United States and Canada. Growth in the biosimilars franchise was partially offset by a 7% ex-FX decline in *Ontruzant*® (trastuzumab-dttb) primarily related to ongoing competitive pressures in Europe. On July 1, 2023, the company launched *Hadlima*, a biosimilar to *Humira* (adalimumab) (a trademark of AbbVie Biotechnology Ltd.) in the United States. Organon already markets *Hadlima* in Canada and Australia.

Established Brands revenue decreased 2% as-reported and was flat ex-FX in the second quarter of 2023, despite the negative impact from Volume Based Procurement (VBP) initiatives in China and the year over year impact of the company's market action taken in the first quarter of 2023 on select injectable steroids, *Diprosan*TM (bethamethasone), and *Celestone Chronodose*TM (bethamethasone), and *Celestone Soluspan*TM (bethamethasone). Offsetting factors included an 18% ex-FX year over year increase in *Atozet*TM (ezetimibe and atorvastatin calcium) which was driven by increased demand in the EUCAN region, as well as 23% ex-FX growth in *Arcoxia*TM (etoricoxib) which was driven by increased volume in the LAMERA region. Year to date, the Established Brands portfolio has grown 1% ex-FX, as 2% volume growth has offset an approximate 1% decline in price across the portfolio. The company continues to expect the Established Brands franchise to achieve flat revenue growth for the full year 2023.

Second Quarter 2023 Profitability

in \$ millions, except per share amounts	Q2 2023	Q2 2022	VPY
Revenues	\$ 1,608	\$ 1,585	1%
Cost of sales	640	588	9%
Gross profit	968	997	(3)%
Non-GAAP Adjusted gross profit ⁽¹⁾	1,012	1,047	(3)%
Adjusted EBITDA ^(1,2)	530	512	4%
Net income	242	234	3%
Non-GAAP Adjusted net income ⁽¹⁾	336	319	5%
Diluted Earnings per Share (EPS)	0.95	0.92	3%
Non-GAAP Adjusted diluted EPS ⁽¹⁾	1.31	1.25	5%
Acquired in-process research & development (IPR&D) and milestones	—	97	NM
Per share impact to diluted EPS from acquired IPR&D and milestones	—	(0.30)	NM
	Q2 2023	Q2 2022	
<i>Gross margin</i>	<i>60.2%</i>	<i>62.9 %</i>	
<i>Non-GAAP Adjusted gross margin ⁽¹⁾</i>	<i>62.9%</i>	<i>66.1 %</i>	
<i>Adjusted EBITDA margin ^(1,2)</i>	<i>33.0%</i>	<i>32.3 %</i>	

⁽¹⁾ See Tables 4 and 5 for reconciliations of GAAP to non-GAAP financial measures

⁽²⁾ Adjusted EBITDA and Adjusted EBITDA margin include \$97 million in the second quarter of 2022 related to acquired IPR&D and milestones, no such expense was incurred in the second quarter of 2023

Gross margin was 60.2% as-reported and 62.9% on an adjusted basis in the second quarter of 2023 compared to 62.9% as-reported and 66.1% on an adjusted basis in the second quarter of 2022. The

year-over-year decline in gross margin is primarily due to product mix as well as employee-related costs and distribution related costs, which increased as a result of inflationary pressures in 2023.

Adjusted EBITDA margin was 33.0% in the second quarter of 2023 compared to 32.3% in the second quarter of 2022. The increase in Adjusted EBITDA margin was primarily a result of \$97 million of IPR&D and milestones in the second quarter of 2022; no such costs were incurred in the second quarter of 2023.

Net income for the second quarter of 2023 was \$242 million, or \$0.95 per diluted share, compared with \$234 million, or \$0.92 per diluted share, in the second quarter of 2022. Non-GAAP Adjusted net income was \$336 million, or \$1.31 per diluted share, compared with \$319 million, or \$1.25 per diluted share, in 2022. The year over year increase in net income was a result of higher Adjusted EBITDA compared with the second quarter of 2022 as well as a tax benefit in the second quarter of 2023 related to earnings outside of the U.S., partially offset by higher interest expense associated with the company's variable rate debt.

Capital Allocation

Today, Organon's Board of Directors declared a quarterly dividend of \$0.28 for each issued and outstanding share of the company's common stock. The dividend is payable on September 14, 2023, to stockholders of record at the close of business on August 18, 2023.

As of June 30, 2023, cash and cash equivalents were \$326 million, and debt was \$8.7 billion.

Full Year Guidance

Organon does not provide GAAP financial measures on a forward-looking basis because the company cannot predict with reasonable certainty and without unreasonable effort, the ultimate outcome of legal proceedings, unusual gains and losses, the occurrence of matters creating GAAP tax impacts, and acquisition-related expenses. These items are uncertain, depend on various factors, and could be material to Organon's results computed in accordance with GAAP.

The company is updating its full year 2023 guidance ranges previously provided on May 4, 2023. The range for full year 2023 revenue is narrowed to \$6.25 billion to \$6.45 billion, which primarily reflects current foreign currency exchange rates. The range for full year Adjusted EBITDA margin is now 31.5% to 33.0% to incorporate the company's current visibility of IPR&D and milestone expenses expected to be incurred in 2023. Organon's financial guidance does not assume an estimate for future IPR&D and milestone payments for business development transactions not yet executed.

Full year 2023 financial guidance is presented below on a non-GAAP basis.

	Previous guidance as of May 4, 2023	Current guidance
Revenues	\$6.150B - \$6.450B	\$6.250B-\$6.450B
Adjusted gross margin	Low-mid 60% range	Unchanged
SG&A (as % of revenue)	Mid 20% range	Unchanged
R&D (as % of revenue)	Upper single-digit	Unchanged
Adjusted EBITDA margin	31.0%-33.0%	31.5%-33.0%
Interest	~\$515 million	~\$525 million
Depreciation	~\$130 million	~\$120 million
Effective non-GAAP tax rate	19.0% - 21.0%	17.5% - 19.5%
Fully diluted weighted average shares outstanding	~257 million	Unchanged

Webcast Information

Organon will host a conference call at 8:30 a.m. Eastern Time today to discuss its second quarter 2023 financial results. To listen to the event and view the presentation slides via webcast, join from the Organon Investor Relations website at <https://www.organon.com/investor-relations/events-and-presentations/>. A replay of the webcast will be available approximately two hours after the conclusion of the live event on the company's website. Institutional investors and analysts interested in participating in the call must register in advance by clicking on this link:

<https://conferencingportals.com/event/jgIqShwa>

Following registration, participants will receive a confirmation email containing details on how to join the conference call, including dial-in information and a unique passcode and registrant ID. Pre-registration will allow participants to bypass an operator and be placed directly into the call.

About Organon

Organon is a global healthcare company formed to focus on improving the health of women throughout their lives. Organon offers more than 60 medicines and products in women's health in addition to a growing biosimilars business and a large franchise of established medicines across a range of therapeutic areas. Organon's existing products produce strong cash flows that support investments in innovation and future growth opportunities in women's health and biosimilars. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey.

For more information, visit <http://www.organon.com> and connect with us on [LinkedIn](#), [Instagram](#), [Twitter](#) and [Facebook](#).

Cautionary Note Regarding Non-GAAP Financial Measures

This press release contains "non-GAAP financial measures," which are financial measures that either exclude or include amounts that are correspondingly not excluded or included in the most directly comparable measures calculated and presented in accordance with U.S. generally accepted accounting principles ("GAAP"). Specifically, the company makes use of the non-GAAP financial measures Adjusted EBITDA, Adjusted gross margin, Adjusted gross profit, Adjusted net income, and Adjusted diluted EPS, which are not recognized terms under GAAP and are presented only as a

supplement to the company's GAAP financial statements. This press release also provides certain measures that exclude the impact of foreign exchange. We calculate foreign exchange by converting our current-period local currency financial results using the prior period average currency rates and comparing these adjusted amounts to our current-period results. The company believes that these non-GAAP financial measures help to enhance an understanding of the company's financial performance. However, the presentation of these measures has limitations as an analytical tool and should not be considered in isolation, or as a substitute for the company's results as reported under GAAP. Because not all companies use identical calculations, the presentations of these non-GAAP measures may not be comparable to other similarly titled measures of other companies. You should refer to Table 4 and Table 5 of this press release for relevant definitions and reconciliations of non-GAAP financial measures contained herein to the most directly comparable GAAP measures.

In addition, the company's full-year 2023 guidance measures (other than revenue) are provided on a non-GAAP basis because the company is unable to reasonably predict certain items contained in the GAAP measures. Such items include, but are not limited to, acquisition related expenses, restructuring and related expenses, stock-based compensation, the ultimate outcome of legal proceedings, unusual gains and losses, the occurrence of matters creating GAAP tax impacts and other items not reflective of the company's ongoing operations.

The company uses non-GAAP financial measures in its operational and financial decision making, and believes that it is useful to exclude certain items in order to focus on what it regards to be a more meaningful representation of the underlying operating performance of the business.

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, this press release includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements about management's expectations about Organon's future financial performance and prospects. Forward-looking statements may be identified by words such as "expects," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "will" or words of similar meaning. These statements are based upon the current beliefs and expectations of

the company's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, an inability to fully execute on our product development and commercialization plans within the United States or internationally; changes in tax laws or other tax guidance which could adversely affect our cash tax liability, effective tax rates, and results of operations and lead to greater audit scrutiny; an inability to execute on our business development strategy or realize the benefits of our planned acquisitions; efficacy, safety, or other quality concerns with respect to marketed products, including market actions such as recalls, withdrawals, or declining sales; political and social pressures, or regulatory developments, that adversely impact demand for, availability of, or patient access to contraception or fertility products; general economic factors, including recessionary pressures, interest rate and currency exchange rate fluctuations; general industry conditions and competition; the impact of the ongoing COVID-19 pandemic and emergence of variant strains; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict its future financial results and performance; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's filings with the Securities and Exchange Commission ("SEC"), including the company's Annual Report on Form 10-K for the year ended December 31, 2022, available at the SEC's Internet site (www.sec.gov).

TABLE 1

Organon & Co.
Condensed Consolidated Statement of Income

(Unaudited, \$ in millions except shares in thousands and per share amounts)

	Three Months Ended		Six Months Ended	
	June 30.		June 30.	
	2023	2022	2023	2022
Revenues	\$ 1,608	\$ 1,585	\$ 3,146	\$ 3,152
Costs, Expenses and Other				
Cost of sales	640	588	1,220	1,149
Selling, general and administrative	451	423	886	794
Research and development	128	106	257	202
Acquired in-process research and development and milestones	—	97	8	97
Restructuring costs	—	—	4	—
Interest expense	132	98	264	195
Exchange losses (gains)	2	(21)	11	(25)
Other expense, net	1	7	7	11
	<u>1,354</u>	<u>1,298</u>	<u>2,657</u>	<u>2,423</u>
Income Before Income Taxes	254	287	489	729
Taxes on income	12	53	70	147
Net Income	<u>242</u>	<u>234</u>	<u>419</u>	<u>582</u>
Earnings per Share:				
Basic	\$ 0.95	\$ 0.92	\$ 1.64	\$ 2.29
Diluted	\$ 0.95	\$ 0.92	\$ 1.64	\$ 2.28
Weighted Average Shares Outstanding:				
Basic	255,341	254,018	254,869	253,802
Diluted	255,953	255,156	256,064	255,105

TABLE 2

Organon & Co.
Sales by top products
(Unaudited, \$ in millions)

	Three Months Ended June 30,						Six Months Ended June 30,					
	2023			2022			2023			2022		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Women's Health												
<i>Nexplanon/Implanon NXT</i>	\$ 159	\$ 56	\$ 214	\$ 134	\$ 61	\$ 195	\$ 272	\$ 107	\$ 380	\$ 250	\$ 116	\$ 366
<i>Follistim AQ</i>	26	44	70	23	35	58	52	73	125	52	66	119
<i>NuvaRing</i>	17	23	40	22	20	42	33	47	80	38	45	83
<i>Ganirelix Acetate Injection</i>	4	29	34	6	25	32	11	53	63	14	47	61
<i>Marvelon/Mercilon</i>	—	29	29	—	31	31	—	67	67	—	54	54
Other Women's Health ⁽¹⁾	27	25	52	29	22	51	53	52	105	56	47	103
Biosimilars												
<i>Renflexis</i>	60	11	70	51	8	59	114	18	132	93	12	105
<i>Ontruzant</i>	12	21	33	12	23	35	25	29	54	19	38	57
<i>Brenzys</i>	—	13	13	—	14	14	—	32	32	—	28	28
<i>Aybintio</i>	—	12	12	—	9	9	—	22	22	—	19	19
<i>Hadlima</i>	—	7	7	—	2	2	—	12	12	—	8	8
Established Brands												
Cardiovascular												
<i>Zetia</i>	2	89	90	2	99	101	4	169	173	5	195	200
<i>Vytorin</i>	1	37	38	3	32	35	3	65	67	5	68	73
<i>Atozet</i>	—	143	143	—	122	122	—	271	271	—	240	240
<i>Rosuzet</i>	—	17	17	—	16	16	—	35	35	—	38	38
<i>Cozaar/Hyzaar</i>	2	69	71	2	91	92	4	152	156	10	176	186
Other Cardiovascular ⁽¹⁾	1	41	41	1	45	46	1	81	82	2	83	85
Respiratory												
<i>Singulair</i>	3	77	80	3	89	92	5	194	199	5	216	222
<i>Nasonex</i>	—	64	64	—	58	58	—	133	133	9	123	133
<i>Dulera</i>	38	10	48	36	12	47	76	18	95	67	21	88
<i>Clarinex</i>	1	38	39	1	34	35	2	77	79	2	70	73
Other Respiratory ⁽¹⁾	13	6	19	11	11	22	25	12	37	23	22	45
Non-Opioid Pain, Bone and Dermatology												
<i>Arcoxia</i>	—	72	72	—	61	61	—	143	143	—	121	121
<i>Fosamax</i>	1	44	44	1	39	40	1	81	82	2	79	81
<i>Diprospan</i>	—	12	12	—	31	31	—	27	27	—	63	63
Other Non-Opioid Pain, Bone and Dermatology ⁽¹⁾	2	67	71	5	71	76	7	127	133	8	137	145
Other												
<i>Proscar</i>	—	24	25	—	26	26	1	51	52	1	50	50
<i>Propecia</i>	2	35	36	2	33	35	4	66	69	3	63	66
Other ⁽¹⁾	2	81	84	7	74	82	4	156	162	15	149	164
Other ⁽²⁾	(2)	41	40	—	40	40	—	79	79	1	78	76
Revenues	<u>\$ 371</u>	<u>\$1,237</u>	<u>\$1,608</u>	<u>\$ 351</u>	<u>\$1,234</u>	<u>\$1,585</u>	<u>\$ 697</u>	<u>\$2,449</u>	<u>\$3,146</u>	<u>\$ 680</u>	<u>\$2,472</u>	<u>\$3,152</u>

Totals may not foot due to rounding. Trademarks appearing above in italics are trademarks of, or are used under license by, the Organon group of companies.

(1) Includes sales of products not listed separately. Revenues from *Marvelon™* and *Mercilon™* were previously reported as part of Other Women's Health. Revenue from an arrangement for the sale of generic etonogestrel/ethinyl estradiol vaginal ring is included in Other Women's Health.

(2) Other includes manufacturing sales to Merck & Co., Inc., Rahway, NJ, USA and other third parties.

TABLE 3

Organon & Co.
Sales by geographic area
(Unaudited, \$ in millions)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Europe and Canada	\$ 467	\$ 443	\$ 867	\$ 880
United States	371	351	697	680
Asia Pacific and Japan	261	291	585	604
China	234	244	459	480
Latin America, Middle East, Russia and Africa	234	216	448	425
Other ⁽¹⁾	41	40	90	83
Revenues	\$ 1,608	\$ 1,585	\$ 3,146	\$ 3,152

(1) Other includes manufacturing sales to Merck & Co., Inc., Rahway, NJ, USA and other third parties.

TABLE 4

Reconciliation of GAAP Reported to Non-GAAP Adjusted Information
(Unaudited, \$ in millions except per share amounts)

	Three Months Ended June 30, 2023						Non-GAAP Adjusted
	GAAP	Spin related Costs ⁽¹⁾	Restructuring	Stock-based Compensation	Amortization	Other ⁽¹⁾	
Revenues	\$ 1,608						\$ 1,608
Cost of sales	640	(10)	—	(4)	(30)	—	596
Gross profit	968						1,012
Gross margin	60.2 %						62.9 %
Selling, general and administrative	451	(44)	—	(17)	—	—	390
Research and development	128	(3)	—	(4)	—	—	121
Acquired in-process research and development and milestones	—	—	—	—	—	—	—
Restructuring costs	—	—	—	—	—	—	—
Interest expense	132	—	—	—	—	—	132
Exchange losses	2	—	—	—	—	—	2
Other expense (income), net	1	(4)	—	—	—	—	(3)
	<u>1,354</u>						<u>1,238</u>
Income before income taxes	254						370
Taxes on income	12	13	—	4	5	—	34
Net income	<u>\$ 242</u>						<u>\$ 336</u>
Earnings per share - Diluted	\$ 0.95						\$ 1.31

(1) Represents one-time costs. Spin-related includes costs from the separation of Merck & Co., Inc., Rahway, NJ, US and Other primarily includes inventory step-up amortization and legal reserves.

	Three Months Ended June 30, 2022						Non-GAAP Adjusted
	GAAP	Spin related Costs ⁽¹⁾	Restructuring	Stock-based Compensation	Amortization	Other ⁽¹⁾	
Revenues	\$ 1,585						\$ 1,585
Cost of sales	588	(6)	—	(3)	(28)	(13)	538
Gross profit	997						1,047
Gross margin	62.9 %						66.1 %
Selling, general and administrative	423	(28)	—	(13)	—	—	382
Research and development	106	(3)	—	(3)	—	—	100
Acquired in-process research and development and milestones	97	—	—	—	—	—	97
Restructuring costs	—	—	—	—	—	—	—
Interest expense	98	—	—	—	—	—	98
Exchange gains	(21)	—	—	—	—	—	(21)
Other expense (income), net	7	(8)	—	—	—	—	(1)
	<u>1,298</u>						<u>1,193</u>
Income before income taxes	287						392
Taxes on income	53	10	—	3	4	3	73
Net income	<u>\$ 234</u>						<u>\$ 319</u>
Earnings per share - Diluted	\$ 0.92						\$ 1.25

(1) Represents one-time costs. Spin-related includes costs from the separation of Merck & Co., Inc., Rahway, NJ, US and Other primarily includes inventory step-up amortization and legal reserves.

TABLE 4 (Continued)

Reconciliation of GAAP Reported to Non-GAAP Adjusted Information

(Unaudited, \$ in millions except per share amounts)

	Six Months Ended June 30, 2023						Non-GAAP Adjusted
	GAAP	Spin related Costs ⁽¹⁾	Restructuring	Stock-based Compensation	Amortization	Other ⁽¹⁾	
Revenues	\$ 3,146						\$ 3,146
Cost of sales	1,220	(20)	—	(8)	(59)	(2)	1,131
Gross profit	1,926						2,015
Gross margin	61.2 %						64.0 %
Selling, general and administrative	886	(90)	—	(32)	—	(1)	763
Research and development	257	(6)	—	(7)	—	—	244
Acquired in-process research and development and milestones	8	—	—	—	—	—	8
Restructuring costs	4	—	(4)	—	—	—	—
Interest expense	264	—	—	—	—	—	264
Exchange losses	11	—	—	—	—	—	11
Other expense (income), net	7	(10)	—	—	—	—	(3)
	2,657						2,418
Income before income taxes	489						728
Taxes on income	70	26	1	8	11	—	116
Net income	\$ 419						\$ 612
Earnings per share - Diluted	\$ 1.64						\$ 2.39

(1) Represents one-time costs. Spin-related includes costs from the separation of Merck & Co., Inc., Rahway, NJ, US and Other primarily includes inventory step-up amortization and legal reserves.

	Six Months Ended June 30, 2022						Non-GAAP Adjusted
	GAAP	Spin related Costs ⁽¹⁾	Restructuring	Stock-based Compensation	Amortization	Other ⁽¹⁾	
Revenues	\$ 3,152						\$ 3,152
Cost of sales	1,149	(10)	—	(6)	(56)	(14)	1,063
Gross profit	2,003						2,089
Gross margin	63.5 %						66.3 %
Selling, general and administrative	794	(53)	—	(23)	—	—	718
Research and development	202	(6)	—	(5)	—	(1)	190
Acquired in-process research and development and milestones	97	—	—	—	—	—	97
Restructuring costs	—	—	—	—	—	—	—
Interest expense	195	—	—	—	—	—	195
Exchange gains	(25)	—	—	—	—	—	(25)
Other expense (income), net	11	(14)	—	—	—	—	(3)
	2,423						2,235
Income before income taxes	729						917
Taxes on income	147	14	—	5	9	3	178
Net income	\$ 582						\$ 739
Earnings per share - Diluted	\$ 2.28						\$ 2.90

(1) Represents one-time costs. Spin-related includes costs from the separation of Merck & Co., Inc., Rahway, NJ, US and Other primarily includes inventory step-up amortization and legal reserves.

TABLE 5

Organon & Co.
Reconciliation of GAAP Income Before Income Taxes to Adjusted EBITDA
(Unaudited, \$ in millions)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Income before income taxes	\$ 254	\$ 287	\$ 489	\$ 729
Depreciation	28	22	56	47
Amortization	30	28	59	56
Interest expense	132	98	264	195
EBITDA	\$ 444	\$ 435	\$ 868	\$ 1,027
Restructuring costs	—	—	4	—
One-time costs ⁽¹⁾	61	58	129	98
Stock-based compensation	25	19	47	34
Adjusted EBITDA	\$ 530	\$ 512	\$ 1,048	\$ 1,159
Adjusted EBITDA margin	33.0 %	32.3 %	33.3 %	36.8 %

(1) One-time costs primarily include costs incurred in connection with the spin-off of Organon, inventory step up adjustments and legal reserves.